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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,490	09/10/2003	Robert B. DeVries	1001.1602101	3452

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
LANG, AMY T	
ART UNIT	**PAPER NUMBER**
3731	

MAIL DATE	DELIVERY MODE
12/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,490	DEVRIES ET AL.	
	Examiner	Art Unit	
	Amy T. Lang	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *11-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/9/2005, 15/15/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention I, claims 1-10, in the reply filed on 9/20/2007 is acknowledged.

2. Claims 11-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/20/2007.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 1-10** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites wherein "the device is deformable about the exposed inner member from a first position to a second position, the exposed inner member provides a force tending to bias the medical device toward the first position." However, it is the examiner's position that the instant specification does not support this limitation.

5. **Claim 2** contains the trademark/trade names Aeromet 100 and Elgiloy. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the specific metal and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-4 and 6-9** are rejected under 35 U.S.C. 102(b) as being anticipated by Tomonto (US 6,425,855 B2).

With regard to **claims 1-4 and 10**, Tomonto discloses a composite medical device (see entire document) comprising an inner superelastic material (80) and an outer plastically deformable material (20, 30, or 40) (Figure 2; column 4, lines 20-50). The superelastic material is further disclosed as Nitinol, a shape memory alloy, and the

plastically deformable material as stainless steel or titanium (column 4, lines 44-50). Therefore, the inner material is more elastic than the outer material. As shown in Figure 2, the medical device comprises at least one region of an exposed inner material where a portion of the outer material (20, 30, or 40) is vacant. Therefore this region would inherently have increased flexibility.

The composite medical device of Tomonto is a stent, which moves from a collapsed position to an expanded position at the target site. Since the inner layer of the stent comprises Nitinol, the inner layer biases the medical device to the expanded position (column 1, lines 43-60).

With regard to **claims 6-8**, the limitations presented are product-by-process and therefore given no patentable weight. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art. Once a device in the prior art has been found which is the same or substantially similar, it is encumbered upon applicant to show a non-obvious difference.

With regard to **claim 9**, it is the examiner's position that the stent of Tomonto overlaps the instantly claimed intravascular filter. When placed in a bifurcated vessel at

the produced fork, the stent can act as a filter. Furthermore, merely calling the device a "filter" does not impart a structure to be patentably distinguished over the prior art.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Tomonto (US 6,425,855 B2) in view of Moore (US 2004/0024444 A1).

Tomonto discloses a composite medical device comprising a stent having an inner superelastic material and an outer plastically deformable material. However, Tomonto does not specifically disclose the outer layer of the stent as coated with a polymeric layer.

Moore discloses a stent that preferably coated with a polymeric layer in order to minimize adverse interaction with the walls of the blood vessel or blood flowing through

the vessel ([0064]). Therefore, it would have been obvious to one of ordinary skill at the time of the invention for the stent of Tomonto to comprise an outer polymeric coating for the advantages disclosed by Moore.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy T. Lang whose telephone number is 571-272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/26/2007
ATL

Todd E. Manahan
SPE 3731